779zsinh Hearing

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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HARBIR SINGH, et al.,

Plaintiffs,

v. 06 CV 00014 (JSR)

HERBALIFE INTERNATIONAL COMMUNICATIONS, INC., et al.,

Defendants.

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July 9, 2007
5:10 p.m.

Before:

HON. JED S. RAKOFF,

District Judge

APPEARANCES

RHEINGOLD, VALET, RHEINGOLD, SHKOLNIK & MCCARTNEY LLP
Attorneys for Plaintiffs
BY: PAUL RHEINGOLD
DAVID B. RHEINGOLD

GOODWIN PROCTER LLP
Attorneys for Defendants
BY: RICHARD A. OETHEIMER
FREDERICK R. McGOWEN

THE DEPUTY CLERK: All rise. Please be seated.
THE COURT: All right. This is a Daubert hearing in the case of Singh versus Herbalife International of America, number 06 Civ. 0014, and it's part of the In Re Ephedra MDL. Will counsel identify themselves for the record.
MR. PAUL RHEINGOLD: Paul Rheingold for the plaintiff, your Honor.
MR. DAVID RHEINGOLD: David Rheingold for the plaintiff.
MR. OETHEIMER: Richard Oetheimer, your Honor, for the defendant Herbalife and Mr. Peterson.
MR. McGOWEN: And Frederick McGowen for Herbalife.
THE COURT: Very good. I guess we should call Dr.

Shields.
MR. PAUL RHEINGOLD: Yes. Dr. Shields, would you come up, please.
LAWRENCE W. SHIELDS,
called as a witness by the plaintiff,
having been duly sworn, testified as follows:
DIRECT EXAMINATION
BY MR. OETHEIMER:
THE COURT: Thank you. Since I'm familiar with Dr. Shields' background and with his expert report, it probably makes sense to have questioning first by counsel for Herbalife.
MR. OETHEIMER: Thank you, your Honor.

BY MR. OETHEIMER:
Q. Good afternoon, Dr. Shields.
A. Good afternoon.
Q. Can I assume that you have a copy of your December 4, 2006 report with you?
A. I do.
Q. Okay, thank you.
MR. OETHEIMER: And the Court has it as well?
THE COURT: I do.
MR. OETHEIMER: Thank you, your Honor.
Q. Dr. Shields, in your report you gave the opinion that with a reasonable degree of medical certainty, Mr. Singh's use of Herbalife on the day of and the months preceding his subarachnoid hemorrhage on May 10th, 2003, more likely than not substantially contributed to his stroke, correct?
A. Yes.
Q. Okay. And, in fact, you assumed and stated in your report that Mr. Singh had taken Herbalife, an Ephedra containing compound, on May 10th, 2003, that is on the day of his stroke. You stated that on page two of your report, correct?
A. That's correct.
Q. Okay. You state that Mr. Singh had used Herbalife on a daily basis for perhaps as long as a year prior to his stroke, and stated that he also used it on the day of this subarachnoid hemorrage, right?

A. Correct.
Q. And actually we can agree, can we not, that Mr. Singh testified under oath at his deposition that he did not take Herbalife on the day of his stroke, isn't that right?
A. That is what he testified to.
Q. And Mr. Singh gave that testimony at deposition in November 2006, the month before you issued your report?
A. That's correct.
Q. And if Mr. Singh took the product in accordance with the Herbalife label, twice daily at 10:00 a.m. and 4:00 p.m --
THE COURT: Wait a minute. I'm sorry.
So, were you aware of that testimony at the time you did your report?
THE WITNESS: I was aware of it at a certain point, but nevertheless, the information that I had was given to me by the patient. So to me that's medical history.
What he said in his deposition, to me, doesn't have the same medical value, even though I know that he was confused

and gets mentally fatigued as a result of his brain injury.
THE COURT: Well, all right, let me just make sure I understand this. He told you that he took Herbalife on the day of his stroke?
THE WITNESS: Yes.
THE COURT: And where did that interview occur?
THE WITNESS: In my office.

THE COURT: Was anyone else present?
THE WITNESS: His wife.
THE COURT: Okay. How long did the interview last?
THE WITNESS: A long time. The -- well, the interview --
THE COURT: A long time is nice, but not nice enough.
THE WITNESS: I'm going to tell you.
THE COURT: Well, please do by answering my question; how long?
THE WITNESS: Well, the interview's integrated with my doing the exam. The entire exam took about two-and-a-half hours.
THE COURT: Okay. And at what point in the exam did he tell you this; what point in the meeting did he tell you this?
THE WITNESS: Fairly early in the exam.
THE COURT: Now, did you review the actual transcript of his deposition before you wrote the report?
THE WITNESS: Well, I don't recall reading the entire deposition. Apparently, it was done in three parts, and I only got one part. And --
THE COURT: Did that part include this testimony, that he had not taken Ephedra on the day of the stroke?
THE WITNESS: I don't recall.
THE COURT: Okay. But at some point you became aware

of it?
THE WITNESS: I became aware of -- yes. I became aware that was his testimony.
THE COURT: And you chose to discount that?
THE WITNESS: I wouldn't say I discounted it. I would say that I gave it less value than what he told me.
I realize that in a given situation, somebody who is brain damaged, it may be that he is giving inaccurate information on either occasion.
But between the two, that is, when he is testifying under oath in a situation which he considers, I would think, adversarial, it would not be the same as when he's talking to me in a doctor's office and giving me a kind of a running account of what had happened.
THE COURT: Well --
THE WITNESS: So --
THE COURT: -- let me make sure I understand your reasoning here. You posit that because of his brain damage, there is a possibility of inaccuracy in either context; yes?
THE WITNESS: That's correct.
THE COURT: But you think that when he is under oath, sworn to tell the truth on the record, in what would seem to be a serious proceeding, that he would be more likely to be

erroneous than when he is in a casual conversation in your office?

THE WITNESS: Absolutely. I consider the history I take to be a medical history.

A legal deposition, to me, is not the same. But I freely admit that either, either version might be incorrect.

THE COURT: Now, if it were correct that he didn't take the last dose on the day of the stroke, would that not be significant, given your testimony that Ephedra's effect on systemic blood pressure wears off within five hours?

THE WITNESS: Well, it's a long question. So, number one, it is my testimony that blood pressure elevation from the oral use of an Ephredra containing compound would have a length of time of, perhaps five hours in terms of its effect on blood pressure. Absolutely true as far as that goes.

But it doesn't change my overall opinion as to what the proximate cause of his ruptured aneurysm was, if he had taken it the day before and not the day that -- of the actual clinical appearance of his subarachnoid hemorrhage.

THE COURT: Well, doesn't it eliminate at least one of the possibilities?

THE WITNESS: You mean in terms of cause from elevated systemic blood pressure?

THE COURT: Yes.

THE WITNESS: Yes. I said that clearly in my deposition.

THE COURT: So, all right. Go ahead. I'm going to go

back to counsel at this point. Go ahead.

MR. OETHEIMER: Your Honor --

Q. Just with respect to the issue of when he took the product that morning, you interviewed --

A. I'm sorry, I didn't --

Q. You interviewed the plaintiff in your office -- you interviewed Mr. Singh in your office November 14th, 2005, correct?

A. Yeah.

Q. And that's when you said he told you that he had taken the product that morning?

A. Yes.

Q. You took notes of that interview, did you not?

A. I did.

Q. And they are marked -- were marked as Exhibit 6 to your deposition?

A. I don't remember the marking, but they were marked.

Q. You took seven pages of handwritten notes?

A. Yes.

Q. And nowhere in those notes did you record that he had taken Ephedra product that morning?

A. Yes, that's true. But you, as you remember in my deposition, I said the notes are not intended to be a record of what he told me. Simply things that would remind me when I did my actual formal note. And --

Q. You did --
A. -- as you might remember in the deposition, there were lots of abbreviations and so on that I couldn't recall exactly what it meant at the time that you asked me about it. So it's just to jog my memory. It's not intended as a, an actual record of the exact things that he said to me.
Q. I did give you an opportunity at your deposition, Dr. Shields, to read and to interpret the entire seven pages of notes.
THE COURT: You know, this is -- I don't want to hear a single further reference, either from the witness or from counsel, as to what he said or didn't say in his deposition. I could care less.
MR. OETHEIMER: Okay.
THE COURT: Let's get to the issue that's before me, not the issue of how the two of you jousted in the past.
MR. OETHEIMER: All right.
Q. You did, and I think, your Honor, your instruction -- I would like -- you did note in your notes that he had had a cup of tea on the morning of the stroke?
A. Correct.
Q. Okay. Now, in your report, Dr. Shields, you also stated that the Herbalife product, that it was your understanding that the Herbalife product contained 21 milligrams of concentrated Ephedra extract and 3 milligrams of caffeine, correct?

A. Yes.
Q. Okay. And that's footnoted at page two of your report?
A. That's correct.
Q. Okay. And, in fact, the Herbalife product label states that three tablets of original green contained 21 milligrams of Ephedrine group alkaloids and 3 milligrams of caffeine, correct?
A. Yes. The label that I was shown later does say that.
Q. You had that label at the time you wrote your report, did you not?
A. Well, you saw the label that I had at the time I wrote my report, and in that it is not clear.
Q. Okay. In any event, would we -- there is no disagreement that your report, in terms of the dosage, that your report is in error, correct?
A. That there is an inaccuracy, yes.
Q. Okay. And your report states that Mr. Singh used three green pills twice a day.
A. Yes.
Q. Is your understanding? So that the mistake in the per tablet dosage of 21 versus 7 milligrams, that error is multiplied by six times, correct?
A. Well, but I never cited the total dosage in my report. I simply footnoted it, the label that I got. So that I never added up the amount.

Q. Okay. In your deposition you added it up at 126 milligrams, correct?
THE COURT: Sustained.
MR. OETHEIMER: Okay.

THE COURT: I seem to have been wasting my breath three minutes ago.

MR. OETHEIMER: I apologize, your Honor. I didn't know how else to do that.

Q. Let me ask this. Ultimately --

THE COURT: Look, let's cut to the chase, because otherwise we will be wasting time. The witness' credibility is, in my view, not at issue on this hearing. Therefore, the fact that he gave prior inconsistent statements is neither here nor there.

Here is what seems to me to be at issue. He made two seemingly material errors in his report, at least, one, he had the dosage three times what it was. He had a fairly enormous dose, as Ephedra goes. And second, he had the timing --

MR. OETHEIMER: Correct.

THE COURT: -- wrong.

The question is whether that has so tainted his report, that he should not be permitted to testify, or whether the report is, either as originally given or as amended, salvageable.

I am already struck by two things, and I hope I will

have to worry about in the rest of the hearing this afternoon. The first is defense counsel's desire to score litigator's points, and the second is the witness' unusually strong defense of this about his prior errors.

Now, the former is regrettable, but immaterial. The latter bothers me, because what I'm hearing so far -- we've only gone five minutes so I may change my mind totally, but I thought I better flag this for the benefit of the witness -- is a seeming desire to defend his bottom line, no matter what, despite what would seem to have been fairly material, on their face, errors.

I am really, for example, quite flabbergasted that this witness seems to be undertaking to arrogate to himself an expertise in what occurs when someone is under oath at a deposition. I wonder if he has any scientific support for his apparent conclusion that people are -- with brain damage are less likely to be accurate in a deposition than in a doctor's office, or whether that's just simply his casual impression that has no scientific basis; it's just his personal opinion. I don't know. I'd like to find out. But he certainly seems to take a very strong position in that regard.

But hold on one minute. I've just been handed a note that I have to deal with on another matter. Just bear with me.

(Pause)

THE COURT: All right, put another question.

MR. OETHEIMER: Your Honor, before I do, could I get a clarification. We obviously have established, the Court said, that there were these two mistakes, and I obviously did inquire of Dr. Shields at deposition to establish that those were mistakes, and he conceded they were, and what effect they would have to his opinion.

And, obviously, what plaintiffs says is bottom line doesn't affect his opinion. But I don't really know how to do this next part without asking him about those answers. I

asked, does the fact that the dose was less, 7 milligrams of, not 21, does that affect your opinion; is there a minimum dose here?
THE COURT: So ask him now.
MR. OETHEIMER: Okay.
Q. Doctor, I asked you, is there a minimum dose -- does the fact that you had the dose wrong in your report impact your opinion?
A. It doesn't impact my overall opinion since it's, the total dose is 42 milligrams, assuming your facts to be in fact facts. So it doesn't alter my opinion since that's above a number that is accepted as being potentially contributory causally to the rupture of an intracranial aneurysm.
Q. And is that because, Doctor, in your opinion in this case any dose except zero, you would consider significant?
A. Yeah, I consider any drug that a patient takes that I'm

seeing significant, so yes.
Q. Okay. And that -- and likewise, your opinion is that it doesn't matter whether he took the product -- whether Mr. Singh took the product that day or he did not?
A. It doesn't change my opinion. It matters, but it doesn't change my opinion.
Q. And is that because your opinion is that any exposure within as much as two weeks before the stroke event could be attributed as causation?
A. In a particular case, that might be the case. But here we're talking about, if I accept your fact as a fact, a day.
Q. Okay. You agree that the product, if it was last taken at 4:00 o'clock the afternoon before, could -- would not have produced any increased systemic blood pressure on the day of the stroke, correct?
A. It wouldn't directly do that.
Q. So when you say it wouldn't directly, you're implying that it could, indirectly?
A. Yes. If it created an intracranial disaster, which raises the blood pressure usually, then I would consider that an indirect effect.
Q. Okay. And you're theory your -- absent the, the --
THE COURT: What is your current theory?
THE WITNESS: That the, that the use of the Ephedra containing product in a dosage, accepting the, as I said, the

facts that have been stated to be facts, 42 milligrams on the day prior -- which is discrepant from what he told me -- would be sufficient to be the proximate cause of his blowing his aneurysm, even though there were other risk factors present.
THE COURT: And how would that happen?
THE WITNESS: By the mechanism of vaso constriction, or I use the term vaso constriction and vasospasm interchangeably. But by the process of narrowing of blood vessels, secondary to the stimulation of alpha one receptors on the blood vessels in the brain.
THE COURT: Now, do I understand it that you did not review the brain images that the treating physician reviewed?
THE WITNESS: I did not see the actual films.
THE COURT: Did you ask for them?

THE WITNESS: Yes. I always do.
THE COURT: And what were you told?
THE WITNESS: I don't recall, but I never received them.
THE COURT: All right. The person you would have been asking was Herbalife's lawyers?
THE WITNESS: I asked, actually, Mr. Rheingold.
THE COURT: Okay. I'm sorry. Mr. Rheingold, plaintiff's lawyer. That's what I meant to say, okay. And he never got them to you?
THE WITNESS: No.

THE COURT: Okay. By the way, just so the record is clear, since there are two Mr. Rheingolds, you're talking about Paul Rheingold?
THE WITNESS: I spoke to David.
THE COURT: Okay. David Rheingold, okay.
Now, there is evidence that the treating physician found no evidence of vasospasm -- I'll get it right -- anyway -- on the brain images; true?
THE WITNESS: No, that's -- no, I don't agree with that, your Honor.
THE COURT: Okay. What is your understanding of what he found?
THE WITNESS: Well, first of all on his actual report he said vasospasm one place, and another place no vasospasm. That's on his actual report.
But of his description of the lesion that was seen in the internal carotid on the left side, he describes an appearance that would be consistent with conditions other than what he called; namely, fibromuscular dysplasia, including spasm, vasospasm in the internal carotid artery could look just like his description of what he saw in the internal carotid artery. So even though he used two different concepts as to vasospasm and no vasospasm, his description itself is one of the patterns that can be seen, not the only one, in a spastic cerebral vessel.

THE COURT: Have you seen -- have you, to this day, now seen the brain images?
THE WITNESS: No.
THE COURT: Let me ask David Rheingold, why not?
MR. DAVID RHEINGOLD: We didn't obtain those films.
THE COURT: Is it correct, as the witness just testified, that he asked you for them?
MR. DAVID RHEINGOLD: I believe so, your Honor.
THE COURT: And so you chose not to follow up on that request?
MR. DAVID RHEINGOLD: Correct. We relied on the written reports.
THE COURT: Okay. So one thing -- I flag this for plaintiff's counsel, not for the witness, whether I should draw an adverse inference from that failure, adverse to the adequacy of this witness' testimony. But you don't have to answer that now.
MR. PAUL RHEINGOLD: Okay. In due course, your Honor.
THE COURT: Well, if you want to answer it now, you

can. I mean, I don't mean to cut you off.
MR. PAUL RHEINGOLD: Well, it hasn't been brought out, the doctor's credentials, your Honor. He's a general neurologist. We're now talking about interpreting neuro radiology or neuro vascular material.
THE COURT: No, that's not the issue. The issue, as I

understand it, is he asked plaintiff's counsel for something that he thought would assist him in rendering his opinion, and plaintiff's counsel chose, for whatever reason, good, bad or indifferent, not to obtain that and provide it to him. And why shouldn't I infer from that that you didn't do that because you thought it might undercut an opinion favorable to you?
MR. PAUL RHEINGOLD: Well, your Honor, we have other motives besides the ones you're attributing to us, and that is that it's not his field. And he hasn't stated yet that he, in looking at these radiographs or whatever they are, could interpret them better than the written report by an expert that he, himself, has now examined.
THE COURT: So you made the determination -- let me make sure I understand what you're saying -- you made the determination that, in your opinion, this wasn't within his purview.
MR. PAUL RHEINGOLD: No, your Honor. I can't say that. That's the way it came out rather than a judgment we made up front. But you also want to create an adverse inference that we made a judgment in the reverse that we wouldn't show it to him because it might somehow change his opinion. That's not the case either.
THE COURT: Well, I don't -- it seems to me problematic that when an expert who you want to call asks to see some data that he believes would be relevant -- indeed, he

just testified he asked for them in all cases -- that you choose not to provide him with that because you make -- you substitute your judgment as to what would be relevant to him or not. That seems to me to be, arguably, the basis for -- forgetting about whether your motive was good, bad or indifferent -- a basis for possibly excluding his testimony.
But, all right, let's continue with the questions.
BY MR. OETHEIMER:
Q. Dr. Shields, we've been speaking about the treating physician, that's Dr. Zablow, correct?
A. Yes.
Q. Okay. In Dr. Zablow's surgical report he noted: No evidence of vasospasm was seen; correct?
A. In one place, yes. And that was his comment.
Q. Excuse me?
A. That was his comment.
Q. Correct. And you, in your testimony in response to the Court's question, referred to his finding of fibromuscular dysplasia, correct?
A. Yes, as a possibility.
Q. Correct. And saying that perhaps that was evidence of vasospasm rather than FMD; was that your suggestion?
A. That the finding was, yes.
Q. Yes. But you correct me if I'm wrong, Doctor, but you,

yourself, without reviewing those films, you cannot say if that

finding represented fibromuscular dysplasia, vasospasm or some other condition, correct?
A. That's correct. But even, even looking at the films, I might not be able to tell, just as this doctor wasn't able to tell.
Q. But you haven't looked at the films?
A. I haven't looked at the films.
But, furthermore --
THE WITNESS: If I may, your Honor?
THE COURT: Go ahead.
THE WITNESS: The doctors treating this patient, as far as I can tell from the records that I got, did not treat him as you would somebody who might have fibromuscular dysplasia. Because what you would do in that circumstance would be to repeat the arteriogram to see in fact if the fibromuscular dysplasia appearance were persistent. Because if it were persistent, it would be suggestive that is in fact a correct diagnosis of what was going on in his neck.
Further, and even perhaps more importantly, would be to investigate the renal arteries, which are those which are most typically involved in fibromuscular dysplasia. And if you find it, there are things that you're supposed to do about it, if it's compromising kidney blood supply. And I didn't see any evidence in the records that I received that either one of those steps were taken.

So it seems to me that the doctors who made that diagnosis or thought it probable, might have either changed their minds -- I don't know the reason they didn't do it. But normally that would be the followup that you would do if you thought you had a patient who had fibromuscular dysplasia.
Q. Okay. Doctor, can we agree there is no radiographic finding of vasospasm at the time of the stroke?
A. No, we can't agree.
Q. Is there a radiographic finding of vasospasm at the time of the stroke?
A. I'm just telling you that the -- what was interpreted as being possibly FMD, could also have been vasospasm.
Q. But you can't say that it was?
A. No, not for sure.
Q. Now, Mr. Singh was a long-time smoker, correct?
A. That's correct.
Q. He had smoked a pack a day for almost 30 years, according to your --
A. According to what he told me, yes.
Q. And you do agree that smoking is an established risk factor for rupture of aneurysm and subarachnoid hemorrhage; do you not?
A. I do. It's in my report.
Q. And the risk of hemorrhagic stroke remains elevated even if someone quit smoking, correct?

A. Yes, over a ten-year period, that's correct.
Q. And Mr. Singh was still smoking at the time of his stroke and had not quit smoking, correct?
A. Absolutely correct.
Q. And you have no basis to exclude smoking as a risk factor in his case, do you?
A. I did not exclude it. I said it was a risk factor.
Q. Right. You characterized as a predisposing risk factor in your report?
A. Yes.
Q. And you cannot exclude smoking as a contributing causal factor in your differential diagnosis?
A. That's correct, and that's how I concluded my report.
Q. And you accept that smoking may have contributed to the formation and growth of the aneurysm?
A. Form -- yeah, well not exactly formation, but growth and further progress.
Q. You believe that his smoking predisposed Mr. Singh to rupture of the aneurysm by weakening the wall of the aneurysm?
A. I do.
Q. And you think the effects, or do you think the effects of smoking also made the aneurysm more subject to rupture from surges or increases in blood pressure?
A. Yes.
Q. And is it your -- and Mr. Singh did have a cup of tea on

the morning of his stroke?
A. That's what he told me.
Q. And you noted that in your --
A. Yes.
Q. -- report? And a cup of tea contains 30 to 100 milligrams of caffeine, is that right?
A. Yes. It's usually closer to 100.
Q. Okay. And a cup of caffeinated tea can produce a surge of systemic blood pressure, can it not?
A. Yes.
Q. And do you accept that the cup of tea that Mr. Singh consumed that morning could have been the precipitant in the rupture of the aneurysm?
A. I think it could have contributed.
Q. Okay. And you do not believe that the Ephedra, if not -- if it was not taken that day, would have had any direct effect on his systemic blood pressure on the day of the stroke?
A. That's correct.
MR. OETHEIMER: Your Honor, I think those are all the questions that I have at this time.
THE COURT: All right.
MR. OETHEIMER: I'll be prepared to argue at the appropriate time.
THE COURT: Let me hear from -- let me hear cross-examination by plaintiff's counsel.

MR. PAUL RHEINGOLD: Thank you, your Honor.
CROSS EXAMINATION
BY MR. PAUL RHEINGOLD:
Q. Dr. Shields, in medicine can you have more than one cause of a disease or condition that appears?

A. Yes. In fact, I said that in my report.
Q. Okay.
THE COURT: The question, though, is why do you think, if you do, that it was more likely than not that Ephedra contributed to this stroke?
THE WITNESS: One big reason is that the natural history of cerebral aneurysms of this type is to never rupture. If we take the most basic statistics that are given, aneurysm prevalence in this country, cerebral aneurysm prevalence in the United States is three -- somewhere between three to 17 percent. But I would simply take a low number, 5 percent of the population. That means we have 15 million aneurysms walking around. 28,000, perhaps, rupture every year. Some of them are reruptures. So even if we were to accept all 28,000 of them, they would be 14,972,000 that didn't rupture. So you need a precipitant.
Now, smoking is a precipitant, and it's also a risk factor. This patient -- but we're still talking about a population of people, a large percentage of which were smoking, and they still don't rupture their aneurysms. So I say that it

is a contributing factor, that is smoking. And Ephedra, also by dint of its design initially or one of its designed uses, which was to constrict alpha one latent blood vessels, which are in your brain, also, alpha one receptors, there is you might say connecting the dot, the dots. You have a potential problem where you add up enough factors, and then the aneurysm blows.
So I think that: A, having the aneurysm; B, smoking; C, taking caffeine with Ephedra, Ephedra, they all add up to blowing the aneurysm. And the dose that he took was sufficient to do it. And the period of time, even the day -- even if we accept what he said in his testimony, sworn testimony, is still within the timeframe that is recognized as being adequate for producing this effect.
Q. Doctor --
THE WITNESS: Those are my reasons.
Q. Excuse me.
THE COURT: Okay.
Q. Do you have an opinion whether, but for the Ephedra, Mr. Singh would've had the rupture of the aneurysm which he had on the date that we know occurred?
A. Yes, I have an opinion, that but for the Ephedra use, he would not have ruptured on that day.
Q. And the amount that he took, when we corrected your report where it comes down to 42 milligrams, rather than some larger

sum, is that opinion changed any way by consideration it was only 42 milligrams?
A. No. 42 is sufficient.
Q. And what's your basis for saying that --
A. Well --
Q. -- that dosage in that range is capable of being the factor that you've assigned to it?
A. Well, first of all, I would say what's reported in the Morgan Stern rehash of the hemorrhagic stroke project would be a piece of literature that's out there.

But on the basis of the way in which Ephedra works, also adds to -- weight to my thinking.
THE COURT: Well, didn't the Morgan Stern study -- which you correctly characterize as a reinterpretation of data that was originally obtained for other purposes -- but didn't the Morgan Stern study conclude, as a statistically significant finding, that doses of Ephedra below 32 milligrams per day are not associated with hemorrhagic stroke?
THE WITNESS: I agree with what you said, except for two things. Number one, the Morgan Stern study, they actually only found seven patients, so it was statistically underpowered. That was what was derived as, on the basis of the study at hand, but not sufficient to come to a conclusion. That's number one.
THE COURT: So, of course, on that basis, we should

disregard it altogether, correct?
THE WITNESS: Well, you never --
THE COURT: Can't take it for some purposes and not for others.
THE WITNESS: Well, I'm taking it for the theory 2 milligrams and above. And I'm not saying it's definite. I'm saying it's the trend in the Morgan Stern study. But it's also consistent with the what we understand about how these drugs or these compounds work, and also it's consistent with what's suggested in the hemorrhagic stroke project itself, where doses as low as 7 milligrams were sufficient because it was PPA.
THE COURT: I'm having a little trouble following what you just said. The Morgan Stern study, one of its few statistically significant findings, assuming you accept the limited population involved, was that doses below 32 milligrams a day are not associated with hemorrhagic stroke. You say, don't give that any particular weight because the number of the population was much too small.
THE WITNESS: Yes. And also --
THE COURT: Okay, okay. Why doesn't that go in both directions?
THE WITNESS: It does. It really does go in both directions.
THE COURT: So the Morgan Stern study is not consistent with the other data that you're just referring to

about 7 milligrams and so forth. It's partly consistent and partly inconsistent?
THE WITNESS: That's right. It's suggestive. The study's suggestive.
THE COURT: Or, or non-suggestive. I mean, it doesn't seem to me you can have it both ways.
THE WITNESS: It's suggestive of the -- no, I -- in all due respect, your Honor, I don't agree.
First of all, the entire study, starting from the HSP, is flawed by their exclusion of patients who died or who had serious neurologic deficit. That excluded a certain number of patients, so the whole picture is considered to be statistically very very shaky.
THE COURT: Right.
THE WITNESS: Nevertheless --

THE COURT: So I'm -- accepting that for present purposes, doesn't it follow, then, that you should forget about the Morgan Stern study; it shouldn't be a factor in evaluating your testimony one way or the other?
THE WITNESS: It's the best we have, and --
THE COURT: All right.
THE WITNESS: -- it substantiates --
THE COURT: Well, then do you want -- yeah, go ahead. I'm sorry.
THE WITNESS: Well --

THE COURT: I agree with you, it's the best we have, which is why the Court referred to it in its Daubert opinion. But I just don't understand that the -- and I'll shut up and let you explain to me -- but I don't understand how you can accept it for certain purposes and disregard it for other purposes.
THE WITNESS: I'm not -- I don't disregard it, your Honor. It demonstrates trends which are consistent with the understanding of the pharmacology of all these substances that we've been talking about. So you have to correlate what happens clinically with your understanding of how this works pharmacologically, physiologically, and you're stuck with these anecdotal type limited studies.
THE COURT: Well --
THE WITNESS: But they hang together.
THE COURT: Well, do they? I mean, in other words, one could conceive of a possibility where -- let's forget about Ephedra for a moment -- let's hypothesize substance X, one could conceive of possibilities where substance X, in even very very small doses could, by its pharmacological operation, bring on strokes or help contribute to their occurrence.
One could also conceive of situation where only when the amount of this hypothetical substance X reached over a certain level, that it was likely to have any effect. One can think of examples in common experience of both those

possibilities. So how do we distinguish which one is true in the case of Ephedra?
THE WITNESS: You have to weigh the individual case. I totally agree with what you've posited. That's why you have to look at each case individually and tease out the particularities of it.
So I didn't get a chance, for example, to discuss the fact that cigarette smoking has its greatest effect on the day that you smoke. Why is that? It's because the pharmacology of the drug, because it induces elastase activity and raises the blood pressure for a short period of time. So you have a nine times greater chance when you smoke that day. You have --
THE COURT: Did he smoke that day or not?
THE WITNESS: He denies smoking to me that day.
THE COURT: Do we know whether he smoked the day before?
THE WITNESS: The assumption is that he did.
MR. PAUL RHEINGOLD: In fact, we're accepting he smoked the day before, but not the day of.
THE COURT: So maybe why wasn't -- why do you think

that, by itself, wasn't sufficient to trigger the stroke?
THE WITNESS: I think any time he smoked he was adding to the burden on his vessels.
However, as I just tried to explain, it's been well demonstrated that if you smoke on the day, you increase your

risk very considerably from two-and-a-half to four times normal risk, to about nine times normal risk. Some people would say seven. I accept nine.
Those episodes on the same day are usually confined to within three hours of having smoked, and that is consistent with the understood mechanism of acute damage to the blood vessels caused by smoking. The elastase piece, very important. What does elastase do? It digests connective tissue, including the internal elastic membrane or internal elastic lamina, which is the last bastion of protection against blowing your aneurysm. But that's an acute effect, the same as the elevation of the blood pressure.
THE COURT: Okay. So along those same lines, Ephedra, at least as I understand your own testimony, Ephedra's effect on -- the direct effect on systemic blood pressure wears off after five hours, right?
THE WITNESS: Of oral use, yes.
THE COURT: Okay. Similar situation to what you've just been describing in terms of smoking, right?
THE WITNESS: Yes.
THE COURT: But there is an indirect way in which Ephedra might, over a longer period of time, cause or contribute to hemorrhagic stroke, and that is what I keep mispronouncing as vasospasm; yes?
THE WITNESS: I would say vasospasm.

THE COURT: Vasospasm. Thank you. That's -- you see, my father is a doctor, but he never taught me the proper pronunciation.
THE WITNESS: Depends where you come from.
THE COURT: On the other hand, he was a gynecologist so it was a different area that he was interested in.
THE WITNESS: I'm interested in that area.
THE COURT: But to ascertain whether in this particular case that there was that indirect vasospasm effect, it would have been helpful, would it not, under your own approach, to have to review those brain images?
THE WITNESS: It would be helpful. But vasospasm is not necessarily demonstrable on an arteriogram.
THE COURT: It wouldn't have been dispositive, but it would have been helpful?
THE WITNESS: It would have been helpful.
THE COURT: Okay. Now, you didn't have that, for whatever reason -- we'll now put that aside for the moment. What was it that you did have that convinced you there was this vasospasm effect?
THE WITNESS: The timing of events, and also the appearance that was described on the reports that I got, and the -- to go back to what I said before, the timing of events, because I don't believe aneurysms rupture for no reason. There's always a reason. And in this case we had several

reasons. One of them was Ephedra.
THE COURT: Well, but at the time you made your original analysis, that was a slam dunk, so to speak, because at that time you were operating under the assumption -- which in your heart I think you still believe was the real reality -- that he took Ephedra on the same day; yes?
THE WITNESS: Yes.
THE COURT: Okay. But, but if -- so you didn't have to reach, at the time you wrote your original report, you didn't have to reach this alternative problem of an indirect effect because you were at least under the assumption that on the day of he took Ephedra, he hadn't smoked; simple case, right?
THE WITNESS: Well, that makes it simpler. But I said many times before that the effect of Ephedra is prolonged, and as long as two weeks in some cases, but three days is well within the range of what is generally accepted, and he was one day.
THE COURT: The indirect effect, the vasospasm?
THE WITNESS: Yes.
THE COURT: Yes.
THE WITNESS: I'm not arguing that it was a blood pressure effect.
THE COURT: Okay. Counsel?
MR. PAUL RHEINGOLD: Thank you, your Honor.

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BY MR. PAUL RHEINGOLD:
Q. Dr. Shields, although did you not see the actual films of the work that was done when they were diagnosing the aneurysm and then treating it, you did read the report of the neuro endo vascular surgeon, is that correct?
A. I did.
Q. Was that, was that and is that still sufficient to you as a basis to give the opinions which you're rendering today?
A. Yes.
Q. In addition to referring to the Morgan Stern article, are there other sources that you've relied upon to know that 42 milligrams of Ephedra taken, let's say, within 24 hours or slightly shorter period of time, can be a cause of the vaso constriction which you've described eventuating in a subarachnoid hemorrage?
A. Well, the main other report that really goes to this is the HSP where low doses, which involved PPA, could produce subarachnoid hemorrhage within three days. They use the three-day time period also, which makes sense. One was derivative from the other, but three days also in that situation. Low dose is seven milligrams, although I freely admit the average dose was much higher.
Q. Okay. In your testimony you're making some analysis or comparison between PPA and Ephedra.
A. I did.

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Q. Would you explain why --

A. They're similar in structure -- pardon me?
Q. Why is it scientifically justified?
A. The molecules look alike. They have similar effects on alpha receptors. Ephedrine has a little bit more effect or more effect on beta receptors. But, basically, the difference between the two molecules really is a methyl group on a nitrogen atom so it's reasonable to analogize from one to the other.
Q. Dr. Shields, if we had not asked you to examine or speak to our client, but instead we had hypothetically told you that we want you to assume that this person had taken 42 milligrams of Ephedra alkaloids the day for a long period of time and last taken at 4:00 p.m. on the day before he had a sudden faint 9:00 a.m. the next morning, would that in any way have changed the opinion which you wrote about in your original report?
A. Well, assuming all the other factors, the cigarette smoking and so on, it would not have changed my opinion.
Q. Thank you, sir.
MR. PAUL RHEINGOLD: That's all the questions we have.
THE COURT: All right. Anything else?
MR. OETHEIMER: I think, your Honor, I'd like to be heard. I don't know that I need to pose any additional questions to Dr. Shields.
THE COURT: All right, Dr. Shields, thank you so much.

You may step down.
THE WITNESS: Thank you, your Honor.
(Witness excused)
MR. PAUL RHEINGOLD: If we're through with the witness, your Honor, may we discharge him?
THE COURT: Sure. Not only may you discharge him, you may even let him leave.
THE WITNESS: Thank you.
(Witness excused)
MR. OETHEIMER: Your Honor, we have -- this is comparable to Curtis Delta, this Ephedra MDL with other comparable cases, and I think having read the transcripts of some of those, I think they are sort of apropos of this.
At the time Dr. Shields wrote his report, he believed that the dosage was three times what it actually was, and he believed that the product had been taken that morning. And that's the basis on which he wrote the report that is before the Court.
We now all understand that those were not the facts, and the facts, the true facts are --
THE COURT: Well, I'm not sure -- actually, on the dosage I think the matter is reasonably clear. On the when he took, you have competing, as I understand it, statements from the witness; one that he made to the doctor and one that he made at his deposition. So I'm not sure that that is so

clearly established one way or the other.
MR. OETHEIMER: I will say, your Honor, that's a little -- in plaintiff's opposition to our motion, and I'll ask Mr. McGowen to pull it -- plaintiff conceded that he did not -- that Mr. Singh did not take the product on the day of the stroke.

THE COURT: Okay.
MR. OETHEIMER: I did hear the testimony.
THE COURT: I see your adversary nodding his head affirmatively, so that's fine.
MR. PAUL RHEINGOLD: For legal purposes, we conceded it. However, the expert explained why it was significant to him to take a history, your Honor.
THE COURT: Okay.
MR. OETHEIMER: And I understand the Court really doesn't want to argue credibility. But I would note -- I don't recall Dr. Shields testifying at deposition to that. And the notes of his interview do not reflect that he was --
THE COURT: Well, it's -- anyway, it's now been conceded so it's --
MR. OETHEIMER: Right, so --
THE COURT: Let me make clear why I don't think credibility is an issue. I don't say that there's never a case where a Daubert determination can't be affected by credibility concerns. But I think in this particular situation -- and I

was motivated, in part, by wanting to move this along -- it seems to me that we have three different opinions here. One is his findings on physical examination of the patient. That has really not been an issue today, and that sounds like he, otherwise relevant, he could testify to that.
Second is his testimony that Mr. Singh's smoking history would predispose him to stroke that could be contributed to by other causes. I want to think about that, but I -- the first part, of course, you don't disagree at all; that is to say, that smoking would predispose one towards a stroke.
I think the nice question here is whether this witness could testify with respect to Mr. Singh -- which is all he's being asked to testify -- is that his background, history, so forth is such that to state it more clearly than the witness did, that by his smoking, he put himself in the position of someone who would be more susceptible than the every day person to the potential effects of Ephedra in possibly causing a stroke. I think that that may be admissible testimony, but that's the second issue.
The third issue, the one that really has been chiefly the point of this hearing is that his opinion that Ephedra more likely than not caused the stroke. I'm very skeptical of that, given the points you just were just alluding to, but I wanted to flag all three areas so we can have them in front of us.

MR. OETHEIMER: Right. I think I can address them. So I think the -- because it's been conceded he didn't take it that day, and because the witness has conceded it could not -- would not have increased his blood pressure that day, he didn't take it that day, an increase in blood pressure as a direct precipitant of the stroke is out. It was in his report, but that's out.
The witness' theory now is this indirect affect, causation through vasospasm. Before I come back to that, on the smoking itself, people -- smoking is the single strongest known risk factor for ruptured aneurysm and hemorrhagic stroke.

It may be true that there are lots of people walking around with aneurysms who don't have strokes, but it is likewise true that lots of people have strokes, and the single strongest association or the two strongest are with hypertension, history of hypertension and a smoking history.

THE COURT: Well, I'm not disagreeing with any of that.

MR. OETHEIMER: Right.

THE COURT: But what I'm saying is it seems to me it might be useful to the jury -- and I, in effect, saw it within this witness' report -- though his report was somewhat conclusory -- that smoking is, in effect, a factor that can cut both ways in this lawsuit.

On the one hand it could, itself, be a cause of

strokes. On the other hand, it could put someone at risk where something else could push you over the line and cause a stroke, and I think that fairly neutral statement is one that the jury maybe needs to know about.

MR. OETHEIMER: Fine. And I'll move to the next, which is, but he's here to give a specific causation opinion.

THE COURT: Right. That doesn't get us to the bottom line.

MR. OETHEIMER: Right. And the question is, one, I guess I want to be clear, I don't accept that there had to be a precipitant that morning. Blood pressure obviously fluctuates up and down. It tends to be highest in the morning. 30 years of smoking does damage to the blood vessels, just with the -- and our expert says the normal sort of ups and downs, you know, of daily life, getting up in the morning, going taking a shower, you could have an aneurysm rupture.

He does -- the one thing we do know is that the plaintiff had a cup of tea that morning. He drinks Lipton tea. It's got caffeine in it. If there had to be a precipitant, and we -- I don't accept there had to be, but why is, Dr. Shields agrees --

THE COURT: Well, there has to be, in the trivial sense, that you can't have an effect without a cause. I guess you can in quantum mechanics, but short of that, no. So --

MR. OETHEIMER: Sure. But the cause can be an

increase in blood pressure.

THE COURT: What you're saying is every day common changes, you know, the fact that --

MR. OETHEIMER: Right.

THE COURT: -- blood pressure changes over the course of a day that, you know, 100 things happen that can affect blood pressure in a normal day.

MR. OETHEIMER: Right.

THE COURT: Someone who is weakened by smoking could be the precipitant effect.

MR. OETHEIMER: Right. So there may not have need to be an exogenous precipitant, but, but the tea could have been, because that clearly does contain caffeine and has an affect on blood pressure.

THE COURT: Well, you're giving plaintiff good ideas for their next --

MR. OETHEIMER: In any event, his opinion clearly is dependent on this theory of the indirect causation through vasospasm. However, what we heard I think a lot, just in the colloquy with the Court, was a lot of what really matters is the general causation, the witness' belief that because of how Ephedrine sort of acts and its biological properties, that it could result in hemorrhagic --

THE COURT: See, the difference is, you know -- and it's interesting what he said about the Morgan Stern study, and

I do think I want to hear from plaintiff's counsel on this, but did seem to me that he was trying to have it both ways with Morgan Stern study. But the Morgan Stern study, I think he correctly said, is far from a perfect study, but it's the best we have. I think that is a fair statement of the reality of that particular study. And that study concluded that 32 milligrams a day or more greatly increases the risk of hemorrhagic stroke. So, the point would be -- and does for a period of several days. So the point would be that, well, okay, ladies and gentlemen of the jury, we'll never know for sure what caused the stroke. Ladies and gentlemen of the jury, we are also reasonably sure that the smoking made him much more susceptible to a stroke at a minimum than he otherwise would have been. Maybe it was tea that morning that set it off. Maybe it was getting out of bed that morning. But as opposed to that possibility, consider the more likely possibility, says plaintiff's counsel, that Ephedra -- which is known to greatly increase the risk of hemorrhagic stroke for a period of several days -- was the precipitant cause; why isn't that a reasonable argument to make to the jury?

MR. OETHEIMER: Let me respond in a couple of levels. I mean, the one thing I see off the bat is I don't think this is Dr. Shields' area of expertise. That's --

THE COURT: And it also varies considerably from where he was originally coming out.

MR. OETHEIMER: Yes, that too. But just to turn back --

THE COURT: Let me just flag for plaintiff's counsel, so he can address it, one -- surely, one of the things that most bothers me about this witness, as I flagged already, is the little bit of rewriting it that, you know, gee, I reached what was an easy conclusion on the data I had. The data is now wrong. I'm reluctant to even give up the data and -- but, by gosh, I'm going to find a way to justify the result even though the data was wrong, because I'll now formulate a possibility even under the new data where it could have come out the same way. That doesn't sound like science. That sounds like human nature in the form of bias.

MR. OETHEIMER: Well, in fact, your Honor, and I know deposition, but when I heard at deposition --

THE COURT: You can refer to the deposition now. I just didn't want to waste time confronting him with prior inconsistencies.

MR. OETHEIMER: When I asked at deposition I said, well, what about the fact that the dose is different than you thought? Is there a threshold dose that we need to have here?

The witness' answer was, any dose except zero. And when I asked about the fact that he didn't take it that day, the witness said, I'm on record as any exposure within two weeks. So I think --

THE COURT: No, he repeated that here today, in effect.

MR. OETHEIMER: Right, had infected his opinion. And those are not consistent with the testimony that this Court has allowed from the generic experts, and it's nothing short of the witness in the guise giving a specific causation opinion substituting his own general causation views. And he's a qualified doctor. He's entitled to opinions, but he's not entitled to invade the province of the generic experts, and he's got to have a basis in the facts of this case for a specific causation opinion.

Stripped of everything else, what we have here is a speculative naked opinion, bottom line that the witness is going to adhere to saying it's my opinion that Ephedra caused the stroke, and change the facts and no problem, because if you got Ephedra within two weeks at any dose, that's good enough for me. And I don't think that cuts it.

Morgan Stern, I don't think it's his province to address Morgan Stern. But Morgan Stern, obviously, as the Court correctly said, found no association below 32 milligrams; found a trend not amounting to a statistically significant association above 32. Obviously there the study was underpowered. It wasn't a study that was designed to study Ephedra. So there are issues with the study.

But Dr. Shields is giving an opinion here that's based

on the theory vaso spasm, that he has no evidence of in the medical records, and he didn't review -- putting aside who's at fault for that -- we got the films to our expert. We didn't have any trouble doing that, and both our expert and the as your Honor both said no evidence of vasospasm.

THE COURT: Well, the plaintiff's counsel hasn't said they had any trouble. They say they chose, for whatever reason, not to show it to him.

All right, let me hear from plaintiff's counsel. Thank you.

MR. PAUL RHEINGOLD: Thank you very much.

This is not a case, your Honor, although it's made to sound that way, of an expert tailoring his opinion once his basis is shifted under, whereas in another case your Honor found exactly that.

In this case Dr. Shields was not careless in obtaining the facts. He may have been a little defensive about how he made his errors. But as a matter of fact, he arrived at them through conversation or through reading a bad label. Maybe I should have given him a better label. But he's not tailoring anything, because in his original report he spoke about vaso constriction or vasospasm as the mechanism in this case, and he did not claim that there was high blood pressure as a cause.

THE COURT: Right. But here's part of the problem. Even if he had read the label, right, he could now be saying

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fairly enough, consistent with Morgan Stern, and the generic testimony that we heard at the earlier Daubert hearing, that this was enough to trigger a vasospasm effect.

MR. PAUL RHEINGOLD: Right.

THE COURT: But as defense counsel points out, that's really not his position. His position is even any amount more than zero, and for any period up to two weeks.

Now, he -- I don't -- he's getting that from wherever, but it's certainly not consistent with what this Court found at the time of the first -- of the overall hearing.

MR. PAUL RHEINGOLD: Nor me, your Honor. And the man made a statement that would be beautiful fun to cross-examine him at trial, because 1 milligram -- obviously, no one accepts as causative. He didn't say it was causative anyway. He said it was significant.

THE COURT: No, but Daubert says it's not just a matter of leaving it to cross-examination at trial.

MR. PAUL RHEINGOLD: For sure. But what he -- although he made a few statements that I wouldn't have made. And as I said, I would enjoy, if I was on the other side of this case, to cross-examine him when this case comes to trial.

Still on the facts of this case, it was 42 milligrams about 18 hours before consumed. So while he said about possibly two weeks, possibly any amount more than zero, that's not the facts of his opinion as he gave it here today. And it

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is the facts, as your Honor pointed out, of Dr. Levine who is the platform that he must work on. Dr. Levine said that it could be anything over 20 milligrams, and he said anywhere from 48 to 72 hours. So this particular case is well within the generic expert's statement, as well as Dr. Heller, and well within what this expert has now been asked to assume as the facts of the case.

THE COURT: It would be a great experiment -- I think some day we should try it -- of having plaintiff's counsel become defense counsel for purpose of cross-examining the expert and vice versa. You know in England, as you may well know, the very same lawyer can be the Prosecutor in one case and the defense counsel in the very next criminal case.

MR. PAUL RHEINGOLD: Yeah.

THE COURT: And it leads to a remarkable balance of view. But, in any event, not to be in our system.

Well, I understand the point you're making.

What about the point, though, that you see that they're making is a little bit different. They're saying it's one thing to say, based on the platform that Dr. Levine gives -- I like that way of putting it -- this patient's history was such that you would expect that, more likely than not, Ephedra would have been the most likely cause or something like that, of tipping him over the -- but he really doesn't say that. He says, I'm going to base this on my own view of what

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the science is here. And my original view, which was perfectly consistent with Dr. Levine and everyone else, was wrong because

of the facts were wrong, but now I'll give a different view based on my erroneous view of the science. How can I allow, under Daubert, someone like that? I have no problem with the other two aspect of his testimony that --

MR. PAUL RHEINGOLD: Yeah.

THE COURT: But on the causality, isn't that a problem?

MR. PAUL RHEINGOLD: My answer, your Honor, is I didn't hear the testimony that way, nor was this correct proper direct or cross-examine the witness. I heard him say that but for adding the Ephedra, it would not have occurred when it did. And his explanation of vaso constriction is not a construct that he made up. It's in Dr. Levine's report and it's in his original report. I think if his testimony were presented systematically, the concern you had would have disappeared.

THE COURT: All right.

MR. PAUL RHEINGOLD: One last point, your Honor?

THE COURT: Please.

MR. PAUL RHEINGOLD: And I said before, I used to be a trial lawyer, I don't do much now. I would love to cross-examine Dr. Shields. But the reason I say that is these things about inconsistency or errors, or if you look at something, are juicy material, but it goes to weight. It goes

to this jury eventually, because the case will be tried here.

THE COURT: I hear you. I used to be a trial lawyer, but I don't do it much now either, so.

Okay. This is very helpful and I'm very glad we had this hearing. It's given me a much more specific feel for this particular witness' testimony and the issues.

I will reserve judgment. I do want to go over the whole thing, including my notes of today's hearing, but I will get you a decision certainly in the next, you know, couple of weeks. So, thanks very much.

MR. PAUL RHEINGOLD: Thank you, your Honor.

MR. OETHEIMER: Thank you, your Honor.

(Adjourned)

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